



AVEXA

Highlights in the Issue:

- Avexa's Capital Raising
- ATC Phase III Trial – Positive Dose Decision
- 22nd International Conference on Antiviral Research
- Option Agreement with Tibotec
- Grant to Further HIV and HCV Research in China
- Antibacterial Program – Activity Against Mupirocin-resistant *Staphylococcus aureus*
- Avexa's Collaborations with China



Chairman and CEO's Letter

Dear Shareholders,

After just the first six months, 2009 is emerging as a landmark year for Avexa on several fronts. In May, we announced Avexa's entry into a six-month, worldwide exclusive option agreement with Tibotec Pharmaceuticals relating to our HIV integrase program. One of the major benefits of working with Tibotec is exposure to their breadth of experience and resources in the anti-HIV drug field, which may enable us to significantly accelerate our programs. The agreement was the culmination of a five-month period of evaluation by Tibotec of multiple compounds from Avexa's HIV Integrase program.

Another very positive development was the recommendation in June 2009 by Avexa's Data and Safety Monitoring Board to progress with the 800mg dose of apricitabine (ATC) for the remainder of its Phase III study. The 800mg dose is considerably easier to formulate into fixed dose combinations, thus increasing the commercial potential for ATC. Given ATC's excellent safety and activity profile, these results allow us to move forward with increased confidence in ATC as a treatment option for HIV patients.

Also in May, Avexa was invited to give an oral presentation at the 22nd International Conference on Antiviral Research (22nd ICAR), which was held in Miami, Florida, US. The presentation, which was about ATC, was given by Dr Susan Cox as part of a clinical

symposium held during the meeting. Further recognition of Avexa's standing as innovators in drug discovery came in the form of a grant awarded under the Australia-China Special Fund for Science and Technology Cooperation to support our collaborative projects in China.

Perhaps the most encouraging aspect of the year to date has been the response to Avexa's 2009 rights issue, which saw the addition of a high-profile US institutional investor to our share registry, and raised A\$18 million in total to help advance our drug pipeline. To those of you who participated in the rights issue, we offer our sincere appreciation for your support and the confidence you have in Avexa, and we repeat our pledge to do everything we can to deliver value to our shareholders.

Mr Nathan Drona
Chairman

Dr Julian Chick
Chief Executive Officer

Avexa's Capital Raising

Avexa has raised approximately A\$18 million through its 2009 rights issue and associated placements. Avexa has a much stronger cash position and balance sheet as a result of this capital raising and is in a good position to advance its drug pipeline. The capital raising exercise was rounded off by an A\$1 million investment by a well respected life science institutional fund based in the US.

Avexa's ATC Phase III Trial – Positive Dose Decision

The initial two-dose component of Avexa's Phase III clinical trial of apricitabine (ATC) has been completed. The overall aim of this Phase III trial is to investigate if it is possible to reduce HIV-1 viral replication in HIV-1-infected patients who have failed treatment with lamivudine or emtricitabine by including ATC in their new treatment regimen. The aim of this first component of the study was to determine which of the two doses of ATC (800mg or 1200mg, both twice daily) would be selected for the remainder of the study.

An independent Data and Safety Monitoring Board (DSMB) was put in place to review the safety and efficacy results when a pre-defined number of patients had reached week 16 of the trial and, from this analysis, make a recommendation as to which dose should be continued (as well as monitoring the overall conduct and safety of the trial). Based on the results of this analysis, the DSMB has concluded that the 1200mg dose is not necessary and recommended selection of the 800mg dose of ATC as the optimum dose to continue. No safety concerns were raised about the 1200mg dose. Patients who had been receiving the 1200mg dose in the study will be switched to the optimum 800mg dose for the remainder of the study and future patients enrolled in the study and randomised to the ATC arm will receive 800mg twice daily for the entirety of the study.

22nd International Conference on Antiviral Research

Avexa was invited to give an oral presentation at the 22nd International Conference on Antiviral Research (22nd ICAR), which was held 3-7 May 2009 in Miami, Florida, US. This conference provides an interdisciplinary forum at which investigators involved in basic, applied and clinical research worldwide can meet to review recent developments in all areas of antiviral research. Dr Susan Cox gave a presentation titled 'Apricitabine: an NRTI with a Unique Barrier to Resistance' as part of a clinical symposium held during the meeting. The symposium featured a small selection of key updates on the progress of antiviral agents, spanning a variety of areas of viral research. Dr Cox's presentation was well received, with much interest in the progress of ATC.

Avexa Signs Option Agreement with Tibotec for HIV-1 Integrase Inhibitor Program

Avexa has entered into a six-month worldwide exclusive option agreement with Tibotec Pharmaceuticals involving its HIV integrase program. The option provides an exclusivity period for the two companies to formalise a collaborative research and license agreement while Tibotec continues to review the Avexa HIV-1 integrase inhibitor drug program portfolio. "We are excited and very encouraged by the results of the preliminary evaluation of HIV-1 integrase inhibitors that Avexa and Tibotec have undertaken to date," stated Dr Julian Chick. "One of the major benefits of working with Tibotec is the breadth of experience and resources in the anti-HIV drug field that they bring to bear which may enable us to significantly accelerate our programs." If Tibotec and Avexa enter into a research collaboration and license agreement, they will harness the medicinal chemistry and *in vitro* resources of both companies to support and accelerate the Avexa HIV integrase program. Treatment of HIV-infected patients with the only currently approved anti-HIV integrase drug results in the selection of viruses that are resistant to that drug; Avexa's lead anti-integrase compounds are able to inhibit this type of resistant virus because they interact with the HIV integrase in a different way from the marketed drug.

"We are excited and very encouraged by the results of the preliminary evaluation of HIV-1 integrase inhibitors that Avexa and Tibotec have undertaken to date," stated Dr Julian Chick.

Avexa Awarded Grant to Further HIV and HCV Research in China

Avexa has been awarded a grant under the Australia-China Special Fund for Science and Technology Cooperation to support its collaborative drug discovery projects in China. The grant is in excess of A\$190,000 and will contribute towards a combined total investment of A\$600,000, which is shared between Avexa and its Chinese partner. This collaboration has been operating for two years, resulting in patent applications on projects involving HIV and hepatitis C virus (HCV). The grant will fund the synthesis and antiviral assay of new antiviral molecules, building on active compounds that have already been discovered during the collaboration. The grant will also fund the establishment of compound-profiling assays, which will be used to screen the Avexa compounds for optimal drug-like properties and to help select potential clinical candidates.

Avexa's Antibacterial Program – Activity Against Mupirocin-resistant *Staphylococcus aureus*

Avexa's antibacterial program has generated a series of novel compounds that have been evaluated as potential antibacterial drugs and a lead molecule (AVX13616) has been selected for pre-clinical testing. AVX13616 has shown promising antibacterial activity against a variety of microorganisms, including strains resistant to other antibiotics such as vancomycin and methicillin. In addition, AVX13616 has been found to be as active as the standard of care antibiotic, mupirocin, in a mouse nasal decolonisation model, but demonstrates a vastly superior dosing regime. Based on these and other results, AVX13616 has been identified for development for topical indications including nasal decolonisation and/or wound infection/catheter-related infections.

Mupirocin is a topical antibiotic that is used to treat skin and soft tissue infections and to eradicate staphylococcal carriage in health care workers and patients. Nasal carriage of *Staphylococcus aureus* is a risk factor for subsequent infection in patients undergoing surgery and intranasal mupirocin treatment before surgery has been found to reduce the risk of *S. aureus* infections after surgery. However, mupirocin resistance in *S. aureus* has been reported and its incidence appears to be increasing in many parts of the world. For example, a study conducted in Canada that investigated mupirocin resistance in methicillin-resistant *S. aureus* (MRSA) found an increase in the

incidence of both high-level and low-level mupirocin resistance in MRSA isolates recovered from patients in Canadian hospitals between 1995 and 2004.

The increasing prevalence of mupirocin resistance in *S. aureus* means that there is a need for antibiotics that are active against mupirocin-resistant strains. In light of this, AVX13616 has been tested against a variety of clinical isolates of *S. aureus* known to be resistant to mupirocin, some of which showed low-level resistance to mupirocin and some high-level resistance. AVX13616 showed good antibacterial activity against all of the isolates tested, with similar activity against isolates with low-level and high-level mupirocin resistance. Some of the isolates tested were also resistant to one or more of six other antibiotics (oxacillin, erythromycin, ciprofloxacin, gentamicin, tetracycline, trimethoprim/sulphamethoxazole) as well as to mupirocin, demonstrating the potential usefulness of AVX13616 in treating *S. aureus* resistant to other antibiotics.

Given the increasing prevalence of mupirocin resistance in *S. aureus*, the activity of AVX13616 against mupirocin-resistant strains in this study is of significance and extends the possible applications of AVX13616.

Avexa's Collaborations with China

China has a long history of traditional Chinese medicines and high quality synthetic organic chemistry and now many companies in China are beginning to move into the pharmaceutical arena. Avexa has set up a number of collaborations with different groups in China, with the aim of combining Avexa's experience in drug development with the expertise in chemistry of the Chinese groups.

Avexa has been working on various HIV projects with Professor Lu Long of the Shanghai Institute of Organic Chemistry (SIOC) since 2005. SIOC has recently moved to a brand new, state-of-the-art chemistry laboratory with around 200 chemists on site and six magnetic resonance (NMR) instruments for chemical analysis. This is a prestigious teaching laboratory, which attracts top

students from all over China. Avexa has shared its drug discovery expertise with Professor Long's group to work on anti-HIV drugs as human therapeutics, whilst the main focus of the in-house work at SIOC was previously agrochemicals. Medicilon, a contract research group in Shanghai, has performed pharmacokinetics studies for Avexa along with studies involving molecular biology and protein expression techniques and bioassay development. Medicilon was one of the first service provider labs in Shanghai directed towards the pharmaceutical industry. In addition, Avexa has an existing formal collaboration in Shanghai, initially as part of the anti-HIV program and now for the HCV program, for which it has recently received funding via a grant from the Australia-China Special Fund for Science and Technology Cooperation (as described above).

Financials

Avexa Limited cash flow report for the nine months ended 31 March 2009

	Current quarter A\$'000
Operating cash flows	
Payments for:	
Staff costs	(4,647)
Advertising and marketing	(288)
Research and development	(25,183)
Leased assets	(192)
Laboratory consumables	(322)
Occupancy	(915)
Consulting	(163)
Legal and professional	(228)
Corporate administration	(160)
Travel and entertainment	(474)
Insurance	(186)
Intellectual property	(366)
Other working capital	(265)
Interest and other items of a similar nature received	1,414
Other - GST refunds	366
- Property sub-rental proceeds	389
- Commercial ready grant	593
Net operating cash flows	(30,627)
Cash flows related to investing and financing activities:	
Physical non-current assets	(69)
Other non-current assets	
- merger proposal costs	(454)
- break fees received	500
Net investing and financing cash flows	(23)
Net decrease in cash held	(30,650)
Cash at beginning of financial year	43,411
Cash at end of March 2009 quarter (Note 1)	12,761

Note 1: In addition to the cash balance of A\$12.76 million at 31 March 2009, the Company raised a further A\$18 million (before costs) through a 1 for 2 Rights Issue to existing shareholders and through related placements of new shares to strategic investors.

Timetable for the next 12 months

Annual Report	September 2009	Quarterly Avexa News	March 2010
Quarterly Avexa News	December 2009	Quarterly Avexa News	June 2009



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Editor's Note

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